EU Declaration of Conformity

HEIDELBErG ENGINEErING

Manufacturer:	
Address:	Heidelberg Engineering GmbH Max-Jarecki-Straße 8 D-69115 Heidelberg Germany
SRN:	DE-MF-000008127

We herewith declare under our sole responsibility that the device(s):

Basic UDI-DI:	0405923700001-ANTERION-GR
Product(s):	**ANTERION**
Risk class (acc. Annex VIII):	IIa, Rule 10

Intended Purpose:

The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for the visualization and measurements of the anterior segment and the measurement of axial length.

- Cornea
  - Shape and thickness
- Anterior segment
  - Anterior chamber width, depth, volume, and angle parameters
  - Lens thickness
- Axial Length
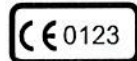- Pupil diameter
- White-to-white distance

The ANTERION also performs calculations to assist users in determining the power of the intraocular lens for implantation.

meet(s) the provisions of the **Regulation (EU) 2017/745** of the European Parliament and of the Council on medical devices in the current consolidated version. All supporting documentation is retained at the premises of the manufacturer.

Notified Body:	TÜV SÜD Product Service GmbH Ridler Str.65 80339 München Germany
Notified Body ID:	CE 0123
Conformity Assessment Procedure:	Annex IX Chapters I and III Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation
EC Certificate No.:	G10 106871 0005 Rev. 00 Expiry date: 2025-12-17

This declaration is valid for all modules/variants/configurations mentioned in the attachment.

Place, Date:	Heidelberg, 08. June 2022
Signature:	
Name:	Arianna Schoess Vargas
Function:	Managing Director
Signed on behalf of:	Heidelberg Engineering GmbH

Attachment

Article no.	Description
88036	ANTERION Platform including • Imaging App
88091 (optional)	• Cornea App
88092 (optional)	• Cataract App
88093 (optional)	• Metrics App